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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/319,156

11/02/1999

GLAUCIA PARANHOS-BACCALA

103514

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12/11/2009

OLIFF & BERRIDGE, PLC

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ALEXANDRIA, VA 22320-4850

EXAMINER

PARKIN, JEFFREY S

ART UNIT

PAPER NUMBER

1648

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/319,156	<b>Applicant(s)</b> PARANHOS-BACCALA ET AL.	
	<b>Examiner</b> Jeffrey S. Parkin	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 7, 9, 14, 15, 26, 60-64, 66 and 67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 7, 9, 14, 15, 60-64, 66, and 67 is/are allowed.
- 6) ☒ Claim(s) 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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**Detailed Office Action**

***Status of the Claims***

Acknowledgement is hereby made of receipt and entry of the communication filed 14 September, 2009. Claims 1, 7, 9, 14, 15, 26, 60-64, 66, and 67 are pending in the instant application. Claim 26 stands withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention (see the restriction requirement mailed 16 February, 2001).

***35 U.S.C. § 119***

Acknowledgement is hereby made of applicants' claim for foreign priority based on FR 97/08816 filed 07 July, 1997. Both a copy of this document and English translation have been received. Accordingly, the foreign priority claim has been entered.

***35 U.S.C. § 102(e)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have

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the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The previous rejection of claims 1, 7, 9, 14, 15, 60, 61, 63, and 66 under 35 U.S.C. § 102(e) as being clearly anticipated by Perron *et al.* (2003, U.S. Patent No. 6,582,703 B2), is hereby withdrawn in response to Applicants' reply.

**35 U.S.C. § 103(a)**

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The previous rejection of claims 62 and 64 under 35 U.S.C. § 103(a) as being unpatentable over Perron *et al.* (2003, U.S. Patent No. 6,582,703 B2), is hereby withdrawn in response to Applicants' reply.

***Request for Rejoinder***

Applicants' request for rejoinder of claim 26 with the examined group is acknowledged. Pursuant to the procedures set forth in M.P.E.P. § 821.04(b), claim 26, directed to the process

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of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, is hereby rejoined and fully examined for patentability under 37 C.F.R. § 1.104. Because all claims previously withdrawn from consideration under 37 C.F.R. § 1.142 have been rejoined, the previous restriction requirement is hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. § 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 U.S.P.Q. 129, 131-32 (C.C.P.A. 1971). See also M.P.E.P. § 804.01.

***35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims

must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claim is incomplete because it omits essential steps, such omission amounting to a gap between the steps. See M.P.E.P. § 2172.01. The claim is directed toward a method for detecting a multiple sclerosis- or rheumatoid arthritis-related retrovirus by simply contacting a biological sample with a nucleic acid corresponding to SEQ ID NO.: 6, 9, or 12. The claimed method steps fail to accomplish the stated objective. A nucleic acid-based assay would require the following minimal steps: 1) obtaining/preparing a biological sample from a patient/subject suspected of being infected with a multiple sclerosis- or rheumatoid arthritis-related retrovirus; 2) transferring any nucleic acids present in said sample to a solid substrate and denaturing said nucleic acids; 3) preparing a probe comprising the nucleic acids of SEQ ID NO.: 6, 9, or 12; 4) contacting the biological sample of step 2) with the probe of step 3) under conditions that permit binding between any putative retroviral nucleic acids in the sample and the probe; 5) washing the sample of step 4) to remove nonspecifically bound nucleic acids; 6) detecting the hybridization complex that remains on the solid substrate. The claims need to carefully specify the hybridization/washing parameters (e.g., high-stringency), as well as, detection means (e.g., how is the probe labeled). Appropriate controls should be employed as well to avoid any false positive results. Applicants are reminded that attempts to claim a process without setting forth any steps involved in the process generally raises an issue of indefiniteness under 35 U.S.C. § 112, second paragraph. For example, a claim which read: "A process for using monoclonal

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antibodies of claim 4 to isolate and purify human fibroblast interferon." was held to be indefinite because it merely recites a use without any active, positive steps delimiting how this use is actually practiced. *Ex parte Erlich*, 3 U.S.P.Q.2d 1011 (Bd. Pat. App. & Inter. 1986).

***Action Is Final, Necessitated by Amendment  
and/or Claim Rejoinder***

Applicants' amendment and/or claim rejoinder necessitated the new ground(s) of rejection presented in this Office action. Applicants are reminded that the provisions of M.P.E.P. § 706.07 govern the propriety of making an Office action final in rejoinder situations. If rejoinder occurs **after** the first Office action on the merits, and if any of the rejoined claims are unpatentable, e.g., if a rejection under 35 U.S.C. 112, first paragraph is made, then the next Office action may be made **final** where the new ground of rejection was **necessitated by applicant's amendment** (or based on information submitted in an IDS filed during the time period set forth in 37 C.F.R. § 1.97(c) with the fee set forth in 37 C.F.R. § 1.17(p)). See M.P.E.P. § 706.07(a) and § 821.04. **Accordingly, THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

### ***Correspondence***

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Larry R. Helms, can be reached at (571) 272-0832. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Respectfully,

/Jeffrey S. Parkin/  
Primary Examiner, Art Unit 1648

10 May, 2009